

### REMARKS

The present application relates to inbred maize plant and seed PH48V. Claims 1-10 are pending in the present application. Claims 2, 7 and 9 have been amended. Applicant acknowledges the addition of claims 11 through 30. No new matter has been added by way of amendment. Applicant respectfully requests consideration of the claims in view of the following remarks.

#### Detailed Action

##### *A. Double Patenting*

Applicant acknowledges the Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c) submitted on April 20, 2005 has obviated the double patenting rejection of record.

##### *B. Claims*

Applicant acknowledges the addition of claims 11 through 30. The new claims do not add new matter as there is support for the claims in the originally filed specification. Support for the specific items can be found within the specification for herbicide tolerance on pages 30-31; insect resistance and resistance to bacterial, fungal, nematode or viral disease on pages 27-30; yield enhancement on page 20; waxy starch and improved nutritional quality on page 20; male sterility on pages 1-3; restoration of male fertility on pages 1-3 and 0-5 generations on pages 3-4. No new matter has been added. Applicant respectfully requests consideration of the claims in view of the following remarks.

#### Rejections Under 35 U.S.C. § 112, First Paragraph

##### *A. Written description regarding Claims 1-10*

Claims 1-10 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states the rejection is repeated for the reasons of record set forth in the Office Action of December 23, 2004. The Examiner states " ... each hybrid would have a completely different set of morphological traits, influenced by the genetic makeup of the second inbred parent". The Examiner further states "that no correlation

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has been demonstrated between structure (gene sequence of one parent inbred) and function (the morphological complement of each divergent F1 hybrid descended from a different second parent)." (Office Action, p. 2-3).

Applicant respectfully traverses this rejection. Applicant reiterates that the written description requirement has been satisfied by the actual reduction to practice of F1 hybrid seed/plant produced by inbred maize line PH48V, by the deposit of a common identifying structural feature of the claimed F1 hybrid seed and plants and by the morphological description of Table 1 of the specification. (See specification, p. 17-19).

In order to satisfy the written description requirement, the Applicant "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). In essence, "the description must clearly allow persons of ordinary skill in the art to recognize that [the Applicant] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989). An Applicant's claims are described where they set forth and define "structural features commonly possessed by members of the genus that distinguish them from others." *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406 (emphasis added). For inventions similar to the present Applicant's, "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). The Board of Patent Appeals & Interferences has also confirmed the sufficiency of a deposit for seed and plants in the case of *Ex Parte C*, 1992 WL 515817 p. \* 5, 27 U.S.P.Q.2d 1492, 1496 (B.P.A.I. 1992), where it stated that "[t]he claimed soybean is described in the specification to the extent that there is no question that appellant was in possession of the invention as of the time the instant application was filed. Because seed is to be deposited in a public depository, the specification is enabling and sets forth the best mode of carrying out the invention."

Further, in order to satisfy the written description requirement, Applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art". *Regents of University of California v. Eli Lilly*, 119 F.3d 1559, 1569, 43 U.S.P.Q.2d 1398, 1406

(Fed. Cir. 1997) (citing as analogous argument *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q.2d 214, 218 (Cust. & Pat. App. 1976)). Consistent with this principal, the Board of Patent Appeals & Interferences, in a case involving the written description requirement as applied to seed and plants, stated "[i]f in making the latter comment the examiner is requiring appellants to have reduced to practice each possible plant within the scope of the claims, such a position is legally incorrect. The specification need only teach one skilled in the art how to make and use the claimed invention. How the specification does so, whether by way of the written word or actual examples, is of no moment." *Ex parte Gerardu C.M. Bentvelsen et al.*, 2001 WL 1197757, p. \*2 (B.P.A.I. 2001). In addition, a claim to the genus of F1 hybrids made with a patented inbred was expressly acknowledged by the U.S. Supreme Court when it stated that "...a utility patent on an inbred plant line protects the line *as well as all hybrids* produced by crossing that inbred with another plant line." *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143; 122 S.Ct. 593, 604; 60 U.S.P.Q.2d 1865, 1873 (2001) (emphasis added). Therefore, Applicant submits that based on the data provided in the specification and the above the function of the hybrid has been correlated to the set of chromosomes originating from the deposited PH48V seed.

In addition to description by structure, the written description requirement may be satisfied by disclosing functional characteristics where there is a correlation between structure and function. The Federal Circuit has stated that the written description requirement may be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics." *Enzo Biochem, Inc.*, 323 F.3d at 964, 63 U.S.P.Q.2d at 1613 (quoting and adopting the USPTO's Written Description Guidelines, 66 Fed. Reg. 1106, No. 4 (2001)). As stated *supra*, Applicant has disclosed sufficiently detailed, relevant identifying characteristics in the Tables provided and therefore has in fact complied with the requirement of written description.

Further, the primary utility of an inbred is in the hybrid it will produce, and Applicant has provided ample description of the hybrids produced by PH48V in the application as filed. (Specification, p. 1, ll. 28-33; pp. 17-19, Table 1; p. 42, Table 3; and pp. 43-49, Tables 4A-4E). As stated in the MPEP, §2163(II)(A)(3)(a)(ii), the written description requirement for a genus

may be satisfied by sufficiently describing a representative number of species actually reduced to practice. These hybrids are thus representative of the hybrids produced using PH48V as a parent. This is sufficient to meet the written description requirement. *See Ex parte Garing*, p. 18 (B.P.A.I. 2005) (stating "[i]n addition, the examiner appears to recognize . . . that appellant's specification describes an exemplary hybrid wherein one parent was a plant of the corn variety [inbred number]. . . Accordingly, it is unclear to this merits panel what additional description is necessary.").

Applicant submits that in accordance with the *Eli Lilly* standard recited by the Examiner, the genus of F1 hybrids encompassed by Applicant's claims 1-10 and new claims 11-30 are described with precise definition in a manner which provides structure sufficient to distinguish an F1 hybrid made with PH48V from an F1 hybrid not made with PH48V. This is because cells and/or chromosomes of inbred line PH48V provide an identifying structural feature possessed by all members of the claimed genus. In addition, new claims 11-30 were added to further characterize the claimed invention. Therefore, since Applicant has deposited the seed of inbred maize PH48V thereby allowing one skilled in the art to identify the F1 hybrids in relation to the structural feature of the claimed invention, the written description requirement of 35 U.S.C. § 112, first paragraph has been met.

The legal standards for the written description requirement are discussed *supra*, and the written description requirement does not mandate a description via morphological and physiological characteristics. Applicant refers the Examiner to the case of *Ex Parte Tanksley*, 37 USPQ2d. 1382. In that case, the Examiner desired that Tanksley claim according to sequence data to "better characterize the cDNA clones" and "facilitate a complete search of the prior art" and issued a 112 first paragraph written description rejection. The Board held that "the section 112 rejection amounts to a requirement . . . that the appellants amend their claims in a specified manner . . . We find no language in the statute or case law which would support that requirement." The Board, in treating the section 112 first paragraph rejection as a § 112 second paragraph rejection, held that "[i]n our judgement, a patent applicant is entitled to a reasonable degree of latitude in complying with the second paragraph of 35 U.S.C. § 112 and the examiner may not dictate the literal terms of the claims for the stated purpose of facilitating a search of the prior art. Stated another way, a patent applicant must comply with 35 U.S.C. § 112, second paragraph, but just how the applicant does so, within reason, is within applicant's discretion." *Id.* at 1386.

One skilled in the art would thus recognize that Applicant was in possession of F1 hybrid seed and plants produced from line PH48V as of the filing date of the application. Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

*B. Enablement regarding Claims 1-10*

Claims 1-10 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner maintains "that each reference teaches the general unpredictability inherent in corn breeding". (Office Action, p. 4).

Applicant respectfully traverses. Inbred maize lines are primarily used to produce F1 hybrid seed and plants. The claimed F1 hybrid seed is routinely and easily produced by crossing a plant from inbred maize line PH48V with a plant from another inbred maize line. Applicant has described how to produce an F1 hybrid from inbred maize line PH48V. (Specification, p. 3, l. 16-p. 4, l. 25). Applicant has also made a deposit of inbred PH48V that fully enables others to obtain the inbred seed needed to make the claimed F1 hybrids.

Applicant reiterates the arguments regarding the references cited by the Examiner as previously presented in the Amendment of April 20, 2005. Applicant asserts the references relate to segregating populations of seed (Kevern), selection within the segregating populations of seed (Carlone), comparison of synthetic populations (Stuber *et al.*), and the making of all possible crosses including F2, 3-way and backcrosses (Melchinger) to produce a population of seed. In contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. An F1 hybrid as claimed is not a genetically mixed population, but rather is highly homogeneous and reproducible because it is made from the highly homogeneous and reproducible inbred maize line PH48V. (Specification, p. 14, lines 17-18). Therefore, the Examiner's assertions are respectfully incorrect because in the present invention the genomic structure of PH48V is shared by the claimed genus of hybrids, due to the highly homogenous nature of the PH48V genetic complement. These are known facts to one of ordinary skill in the art of inbred maize lines and are sufficient to provide the distinguishing

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characteristics necessary to comply with 35 U.S.C. § 112, first paragraph. The Applicant has thus provided "distinguishing characteristics" of the claimed genus. As explained above, these specific identifying characteristics are the cells and/or chromosomes of PH48V described in the deposit of the present application and present in the claimed F1 hybrid genus. The cells and/or chromosomes are present in the genus of F1 hybrids made with PH48V and absent in the genus of F1 hybrids not made with PH48V. To require Applicant to further describe aspects of the claimed invention that are not the point of patentability of the genus extends the written description requirement beyond the legal standard. Thus, Applicant respectfully asserts the arguments set forth by the Examiner do not apply to the presently claimed invention.

Applicant has described how to produce an F1 hybrid from inbred maize line PH48V. In addition, one skilled in the art of corn breeding would know that the F1 plants and seed of claims 1-10 can routinely and easily be produced by crossing PH48V with another inbred maize line. Accordingly, Applicant submits that claims 1-10 are fully enabled and have fully satisfied the legal standards for enablement.

#### Summary

Applicant acknowledges that claims 1-10 are deemed free of the prior art. The Examiner states the prior art fails to teach or fairly suggest inbred maize plant PH48V, or method of using it. This clearly indicates that maize inbred line PH48V as a whole is considered to be distinguishable from the prior art for the purposes of novelty and non-obviousness.

#### Conclusion


In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

This Amendment accompanies a Request for Continued Examination (RCE). Please charge Deposit Account No. 26-0084 the amount of \$790.00 per the attached RCE Transmittal. Please also charge Deposit Account No. 26-0084 the amount of \$700 for 10 additional claims over 20 (\$50 each) and 1 additional independent claim over 3 (\$200 each). No other fees or extensions of time are believed to be due in connection with this amendment; however, consider

this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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